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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,874	10/31/2003	Francesco Greco	P-10183.02US	2016

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EXAMINER	
SZMAL, BRIAN SCOTT	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,874	GRECO ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-30 and 32-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,21,23-30,32,33 and 35-46* is/are rejected.

7)☒ Claim(s) *22,34,47 and 48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6-6-2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Specification

1. The abstract of the disclosure is objected to because the Abstract exceeds 150 words. Correction is required. See MPEP § 608.01(b).

Claim Objections

2. Claim 27 is objected to because of the following informalities: In line 1, "the fourth inside diameter" lacks antecedent basis. The claim appears it should refer to Claim 26 instead of Claim 20. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 43-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Dormandy, Jr. (5,779,672).

Dormandy, Jr. discloses a detachable occlusion balloon on a catheter and further discloses an elongated catheter comprising a first outer diameter, a first proximal end and a first distal end; an elongated means for carrying the expanding means having a second proximal end, a second distal end and a second outer diameter, the second proximal end of the carrier and the first distal end of the catheter being configured to permit the first distal end of the catheter to matingly engage the second proximal end of the carrying means, the second outer diameter of the carrying means being similar to the first outer diameter of the catheter; a disposable means for expanding formed from

an expandable and resilient biocompatible material, the expanding means having a lumen disposed between a third proximal end and a third distal end thereof, the lumen having at least a third inside diameter, the second diameter of the carrying means and the third diameter of the expanding means being configured to permit the expanding means first to be slideably mounted onto the carrying means and second to be slideably moved from the carrying means onto the catheter when the second proximal end of the carrying means is matingly engaged with the first distal end of the catheter; providing the elongated catheter; providing the disposable balloon system; engaging the first distal end of the catheter against the second proximal end of the carrier, and sliding the balloon onto the catheter from the carrier. See Figures 7 and 9a-9c; Column 3, lines 47-54; Column 4, lines 30-63.

5. Claims 20, 21, 23, 24, 26-30, 32, 33, 35, 36 and 38-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Dormandy, Jr. (5,779,672) in view of MatWeb (material spec sheets for medical grade silicone).

Dormandy, Jr., as discussed above, discloses a detachable occlusion balloon on a catheter and further discloses a lumen disposed between a third proximal end and a third distal end thereof, at least a third inside diameter; wherein the second diameter of the carrier and the third diameter of the balloon are configured to permit the balloon first to be slideably mounted onto the balloon carrier and second to be slideably moved from the carrier onto the catheter when the second proximal end of the carrier is matingly engaged with the first distal end of the catheter; the third inside diameter of the lumen is configured to engage the second outside diameter of the carrier near or at the proximal

and distal ends of the balloon; the length between the proximal and distal ends of the balloon is selected from the group consisting of ranging between about 5 mm and about 100 mm; the balloon has a wall thickness selected from the group consisting of ranging between about 0.1 mm and about 0.5 mm; the lumen further comprises a fourth inside diameter that is greater than the third inside diameter, at least portions of the lumen disposed near or at the third proximal end and the third distal end having the third inside diameter, at least portions of the lumen disposed between the third proximal end and the third distal end having the fourth inside diameter; the fourth inside diameter is selected from the group consisting of between about 2 mm and about 20 mm, ranging between about 4 mm and about 15 mm, and ranging between about 6 mm and about 10 mm; the balloon comprises medical grade silicone; the balloon comprises a material having a tensile strength selected from the group consisting of ranging between about 200 psi and about 3000 psi, and ranging between about 1000 psi and about 2000 psi; the balloon comprises a material having a Shore durometer hardness selected from the group consisting of ranging between about 5 ShA and about 100 ShA, and ranging between about 30 ShA and about 70 ShA; an elongated balloon carrier having a second proximal end, a second distal end and a second outer diameter, the second proximal end of the carrier and the first distal end of the catheter being configured to permit the first distal end of the catheter to matingly engage the second proximal end of the carrier, the second outer diameter of the balloon carrier being similar to the first outer diameter of the catheter; and (b) a disposable balloon formed from an expandable and resilient biocompatible material, the balloon having a lumen disposed between a third proximal

end and a third distal end thereof, the lumen having at least a third inside diameter, the second diameter of the carrier and the third diameter of the balloon being configured to permit the balloon first to be slideably mounted onto the balloon carrier and second to be slideably moved from the carrier onto the catheter when the second proximal end of the carrier is matingly engaged with the first distal end of the catheter. See Figures 7 and 9a-9c; Column 3, lines 47-54; Column 4, lines 30-63.

Even though Dormandy, Jr. does not explicitly disclose the physical properties of the silicone balloon, MatWeb provides evidence that a medical grade silicone would have the claimed properties, and therefore, Dormandy, Jr. inherently discloses the claimed physical properties of the silicone balloon. Furthermore, based on the specification and drawings of Dormandy, Jr., the fourth inside diameter is clearly disclosed by Dormandy, Jr. due to the outside diameter of the mandrel in light of the outside diameter of the balloon as seen in Figure 7.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 25 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dormandy, Jr. (5,779,672) and MatWeb as applied to claims 20 and 32 above, and further in view of Johnson et al (5,263,962).

Dormandy, Jr., as discussed above, discloses a detachable occlusion balloon on a catheter, but fails to disclose the third diameter is selected from the group consisting of ranging between about 3 mm and about 15 mm, ranging between about 4 mm and about 12 mm, ranging between about 5 mm and about 10 mm, and ranging between about 6 mm and about 9 mm.

Johnson et al disclose a balloon catheter and further disclose the third diameter is selected from the group consisting of ranging between about 3 mm and about 15 mm, ranging between about 4 mm and about 12 mm, ranging between about 5 mm and about 10 mm, and ranging between about 6 mm and about 9 mm. See Column 4, lines 7-10.

Since both Dormandy, Jr. and Johnson et al disclose balloon catheters, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the diameter of Dormandy, Jr. to include an alternative diameter within the claimed ranges, as per the teachings of Johnson et al, since it is well known in the art that catheter diameters can vary depending upon the desired use and placement of the catheter.

Allowable Subject Matter

8. Claims 22, 34, 47 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BS

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